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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631

7590 11/21/2006

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,920	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 08/28/2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61 and 67-84* is/are pending in the application.

4a) Of the above claim(s) *82-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *61 and 67-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/05; 05/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group XVI (claims 61 and 67-81) in the reply filed on 28 August 2003 is acknowledged. The traversal is on the ground(s) that Group XII (82-84) should be examined along with the elected Group. This is not found persuasive because as noted in the Restriction/ Election Requirement mailed June 26, 2006 these two Groups read on two different methods with two different method endpoints.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 61 and 67-84 are pending.

Claims 1-60 and 62-66 have been cancelled.

Claims 67-84 have been added.

Claim 61 has been amended.

Claims 82-84, drawn to non-elected inventions are withdrawn from examination.

Claims 61 and 67-81 are examined on the merits.

Priority

3. Applicants' claims encompass an acronym, CR1 and the polynucleotide sequence identified as SEQ ID NO: 1320. This examined sequence was not of record in the eight continuation-in-part (CIP) applications, which Applicants believe they derive benefit. The Examiner has reviewed them all as does not

note the sequence or acronym. Consequently, Applicants' are afforded the priority date of the instant application, September 23, 2003.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 61 and 67-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants have amended claim 61 to include the term "CR1" in the context of detecting this molecule in a patient sample for evidence of differential expression and consequently diagnosing cancer. New claims 67-81 have been added also reading on this detection method of CR1 gene expression. Applicants assert support for the amendment and new claims can be found in specific paragraphs of the specification and Table 113, see Remarks submitted August 28, 2006, page 6, 2nd paragraph. The Examiner has reviewed the entire specification, as well as tried to locate Table 113. Table 113 seems not to be of record in the specification and the specification does not note the acronym, CR1 and its meaning. The method for diagnosing cancer comprising detecting

evidence of differential expression of CR1 in a patient is not supported by the specification as-filed. Applicants are invited to further specify where in the disclosure by page and paragraph support for this method can be found. In the event support is not pointedly expressed Applicants should delete the new matter.

6. Claims 61 and 67-81 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' claim method for diagnosing cancer comprising detecting CR1 in a patient sample and diagnosing cancer comprising determining the level of expression product having at least 98% and 95% sequence identity to a sequence of SEQ ID NO: 1320, or a complement thereof. The written description is not commensurate in scope with these method claims drawn to a method of detection of mRNA sequences 98% and 95% sequence identical to SEQ ID NO: 1320 or complements thereof, which have not been adequately described nor evidenced to be in the possession of Applicants. Applicants seem to only be in possession of SEQ ID NO: 1320. "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was 'ready for patenting' such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by

describing distinguishing identify characteristics sufficient to show that the applicant was in possession of the claimed invention", see Official Gazette, 1242 OG 172, January 30, 2001.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of nucleotide sequences having 98% or less identical to SEQ ID NO: 1320, as well as nucleotide sequences 95% sequence identical to complements thereof, and conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The product itself is required. Applicants have not described nucleotide sequences at least 98% and 95% identical to SEQ ID NO: 1320, as well as complements thereof with sufficient particularity such that one skilled in the art would recognize that the Applicants had possession of the claimed invention. See *Fiers v. Revel*, 25

USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement, which defines a genus of nucleic acids by only their functional activity, does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 61, 67-72 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Salomon et al. (Endocrine-Related Cancer 7: 199-226, 2000). Salomon discloses method of detection and subsequent diagnosing of increased expression of human cripto (CR-1) in human colon carcinoma, breast carcinoma and other cancers, see Abstract; page 213, Expression of cripto...section; and Table 5 on page 214. "CR-1 mRNA and protein are expressed at high levels in... primary and metastatic colorectal cancers. CR-1 mRNA expression by Northern blot analysis was detected in 68% of primary or metastatic human colorectal cancers but only in 3% of noninvolved adjacent colon mucosa.", see page 214, Colon section. Elevated CR-1 protein expression was also observed using immunohistochemistry in colon tumor and less in noninvolved normal colonic mucosa adjacent to tumor or adenomas, see page 214, Colon section. "CR-1

mRNA and protein can be detected in...approximately 80% of human primary infiltrating breast carcinomas...and in only 13% of noninvolved adjacent breast tissue samples.", see page 215, Breast cancer section.

9. Claims 61, 67, 68, 71, 72, 75, 76 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Guc et al. (Eur. J. Haematol 64(1): 3-9, January 2000). Guc discloses surface expression of complement receptor 1 (CR1) was lower in acute myeloblastic leukemia (AML) in comparison to their normal counterparts, 5.5 fold lower. And CR1 mRNA expression was significantly lower in acute lymphoblastic leukemia (ALL) than in the control group, see Abstract.

10. Claims 61, 67-76, 80 and 81 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 6,569,662 B1 (filed July 19, 2000). U.S. Patent # 6,569,662 discloses a complement of SEQ ID NO: 1320, see attached database sheet. This complement is sequence 259 identified as a polynucleotide that encodes *Homo sapiens* CR1 precursor protein, see columns 123 and 124. The patent discloses detection of the presence or amount of polynucleotides or polypeptides in a sample for the diagnosis of metastatic cancer, acute and chronic leukemias, lymphomas, breast cancers and colon cancer, see column 4, lines 30-49; column 38, section 4.7.11. "The presence or increased expression of a polynucleotide/polypeptide of the invention may indicate a hereditary risk of

cancer, a precancerous condition, or an ongoing malignancy.", see column 38, lines 44-48.

Even though the patent does not explicitly note of the comparison of presence or amount of polynucleotides or polypeptides is relative to expression in normal tissue. It is reasonable to conclude the assessment of CR1 expression was based upon differences discerned between experimental samples (i.e. leukemia and other cancers) and normal controls.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
13 November 2006